# **EXHIBIT D**

LAW OFFICES

### WAGSTAFF & CARTMELL LLP

THOMAS W. WAGSTAFF
THOMAS P. CARTMELL
MARC K. ERICKSON
JONATHAN P. KIEFFER
THOMAS L. WAGSTAFF\*\*
ERIC D. BARTON†!!
BRIAN J. MADDEN
JEFFREY M. KUNTZ
THOMAS J. PREUSS
THOMAS A. ROTTINGHAUS
TYLER W. HUDSON\*\*\*
DIANE K. WATKINS\*\*\*

JOHN P. O'CONNOR+† P.J. O'CONNOR+† DANIEL J. LOBDELL† 4740 GRAND AVENUE - SUITE 300 KANSAS CITY, MISSOURI 64112

(816) 701-1100 FAX (816) 531-2372

BRANDON D. HENRY
SARAH B. RUANE
CHRISTOPHER L. SCHNIEDERS H
VANESSA H. GROSS
ADAM S. DAVIS
JACK T. HYDE
DAVID M. MCMASTER
JOAN D. TOOMEY
ANDREW N. FAES\*
ASHLEY D. DOPITA\*

SCOTT M. CROCKETT† PHILLIP P. ASHLEY\*† DARYL J. DOUGLAS\*†

March 04, 2013

Christy D. Jones Donna B. Jacobs Benjamin M. Watson BUTLER SNOW PO Box 6010 Ridgeland, MS 39158

RE: Pelvic Mesh

Dear Christy:

I am writing to set forth items of discovery that plaintiffs request be expedited prior the depositions of the TVT witnesses, the first of which is Susan Lin, scheduled for March 12<sup>th</sup> and 13<sup>th</sup>. This request involves establishing the "final" in-use versions of the IFU's for the TVT products, as well as the "final" in-use versions for the SUI patient brochures. In order to avoid wasting valuable deposition time and the possible need to re-depose witnesses, it is necessary to establish from the onset the final versions of these documents so the examination of witnesses can occur in an orderly and efficient manner.

Riker Danzig has already provided a list of the IFU's in use for the various products at issue in this litigation, including the first day of use and the last day of use, attached hereto as "Exhibit A". A list of the final in-use versions of the POP Patient brochures and dates of use have also been produced, attached hereto as "Exhibit B". However, to the best of my knowledge, the same has not been done for the SUI patient brochures at this time.

- 1. For each of the TVT Products, please produce the original patient brochure(s) utilized from 1998 to the present, if not already produced. Also provide the official dates of first and last use, and identify by bates range.
- 2. Please also produce any so-called "disease state" SUI product brochures prepared or distributed by Ethicon or J&J from 1998 to the present regardless of whether they specifically reference Ethicon or J&J products, if not already produced. Also provide the official dates of first and last use, and identify by bates range.

#### LAW OFFICES

### WAGSTAFF & CARTMELL LLP

Christy D. Jones Donna B. Jacobs Benjamin M. Watson March 4, 2013 Page 2

- 3. The version of the TVT "classic" IFU designated as the final version in use from 01-16-01 to "unavailable" (ETH.MESH.02340370) appears to be missing significant areas of text from multiple areas of the document. Please confirm that this version of the document with the missing text does indeed represent the final version of the IFU. If it does not, please reproduce the correct document and amend the IFU Index and Production Bates Range Chart if necessary.
- 4. The version of the TVT "classic" IFU designated as the final version in use from 04-07-2006 through 10-07-2008 (ETH.MESH.02340250) appears to have no English version of the label contained within the document. Please confirm that this version of the document with the missing text does indeed represent the final version of the IFU. If it does not, please reproduce the correct document and amend the IFU Index and Production Bates Range Chart if necessary.
- 5. The version of the TVT "classic" IFU designated as the final version in use from 11-29-10 to present day (ETH.MESH.02340402) appears to be missing significant areas of text from multiple areas of the document similar to the IFU described in #3 above. Please confirm that this version of the document with the missing text does indeed represent the final version of the IFU. If it does not, please re-produce the correct document and amend the IFU Index and Production Bates Range Chart if necessary.
- 6. The TVT "classic" device received FDA clearance on 01-28-1998, yet there is no IFU designated as in-use prior to 01-16-2001. While we understand that the TVT "classic" may not have been marketed in the United States during that entire time period, any IFU's in use between 01-28-1998 and 01-16-2001 are relevant to this litigation regardless of whether or not they were used in the United States. Please produce any such TVT IFU's in use during that time frame if not already produced. Also provide the official dates of first and last use, identify by bates range, and amend the IFU Index and Production Bates Range Chart if necessary.
- 7. For the TVT-AA and TVT-D, please produce any IFU's used during those products' lifecycle, if not already produced. Also provide the official dates of first and last use and identify by bates range.

#### LAW OFFICES

### WAGSTAFF & CARTMELL LLP

Christy D. Jones Donna B. Jacobs Benjamin M. Watson March 4, 2013 Page 3

8. With regard to the version of the TVT "classic" IFU being designated as in-use from 01-16-01 to "unavailable", please provide an explanation for why the last use date for this particular IFU is "unavailable." Also, please identify and provide the source of the underlying data utilized to create the first use date and last use date on the IFU Index and Production Bates Range Chart.

All of the above items were requested in the New Jersey litigation over a year ago, and are within the scope of existing discovery requests in the MDL, so they should not be construed as new requests. There are other production issues that we will be addressing under separate cover. Please let us know how long you estimate it will take to respond to these requests.

Best regards.

Very truly yours,

James 1. Castrell

Thomas P. Cartmell

TPC/mg Enclosure cc: Bryan Aylstock Renee Baggett

# EXHIBIT A

In re Pelvic Mesh/Gynecare Litigation

### IFU Index and Production Bates Range Chart

	Product	Artwork Approval Date	Production Prefix	Start Bates	End Bates	RMC/LAB#	First Ose Oute	Last Use Date
	Gynemesh PS	24-Sep-08	ETH MESH	02342218	02342249	389766 LAB-0012266 [1]	4-Dec-08	To present day
	Gynemesh PS	26-Sep-08	ETH MESH,	02342250	02342277	389593.R03	12-Dec-09	To present day
	Gynemesh PS	May-05	ETH MESH	02342278	02342290	389593 R02	8-สมา-05	11-Dec-08
į	Gynemesh PS	Unavailable	ETH MESH	02342194	02342217	389593,R01	20-Mar-03	30-Mar-06
5	Prolene Mesh	28-Apr-10	ETH MESH.	02342152	02342154	389392 RQ4	18 JUN, 2010	To present day
Ġ.	Prolene Mesh	4-Jun-99	ETH MESH,	02342102	02342102	389392,R02 LAB-0010365	29-May-99	3-Jul-11
7	Frolene Sofi	10-Nov-60	ETH MESH	02342101	02342101	389578 R02 LAB-0010386	5-Dec-00	To present day
8	Prolene Soft	Jun-10	ETH MESH	02342094	02342096	389737R04 LAB-0010432	23-Aug-10	To present day
ã	Profese Soft	11-Apr-08	ETH.MESH	02342097	02342097	389737	13-Apr-09	22-Aug-10
ņ	Prolift	10-May-10	ETH MESH	02341658		P19070/H LAB-0011099 [2)	11 May 2010	To present day
1	Prolift	30-Sep-09	ETH MESH	02341734	02341809	P19070/G LAB-0011099 [1]	1-Oct-09	7-May-10
5	Prolift	12/14/2007	ETH MESH	02341454	02341521	P19070/E	17-Dec-07	24-Sep-09
	Prolift	1/12/2005	ETH MESH	02341522	02341589		11-Jan-05	13-Dec-07
4	Prolift + M	31-Mar-10	ETH,MESH	02341954	02342093		11-May-10	To present day
5	Prosima	17-Mar-10	ETH MESH	02341398	02341453	P21070/D LAB-0011036 Rev 2	18-Jun-10	To present day
6	TVT	25-May-10	ETH,MESH,	02340402	02340470	P15506 LAB-0012841/31	29-Nov-10	To present day
7	TVT	9-Oct-08	ETH MESH	02340504	02340567	P15506/E LAB-0012841(2)	13-Oct-08	22-Nov-10
R	TVT	8-Nov-05	ETH.MESH	02340250	02340395	P16506/E/	7-Apr-08	7-Oct-08
	TVT	7-Mag-05	ETHIMESH	02340471	02340503		11-Feb-05	7-Apr-06
3	ÍV)	11-001-01	ETH MESH	02340308	02340359		22-Dec-03	21-Feb-05
	Ϋ́ντ	Jan-01	ETH MESH	02340370	02340401	P15508	16-Jan-01	unevalleble
2	TVT-Abbrevo	17-Jul-10	ETH MESH.	02341203	02341267		10 Sep 2010	To present
3	TVT-Exact	23-Feb-10	ETH MESH	02341119	02341202	LAP-0012869[1]	4 May 2010	To present day
1	171-0	17-Mar-10	ETH MESH	02340902	02340973	P18070/E LAB-0010875 [2]	12 MAY 2010	To present day
e,	TVT-0	11-Apr-08	ETH MESH	02341047	02341118	P18070/O LAG-0010875 (1)	23 Apr 2008	07 May 2010
	TVT-O	3-Jun-05	ETH MESH	02040974	02341048		25 May 2005	29 Apr 2008
	TVT-O	7-Mar-05	ETH MESH	02340756	02340828	P18070/B	07 Mar 2005	19 May 2005
3	TVT-O	28-Oct-03	ETH MESH	02340829	02340901	P18070/A	07 Jan 2004	04 Mar 2005
9	TVT-\$	30-Nov-05	ETH MESH	02340568	02340755	P20070A LAB-0010892	16 Dec 2005	To present day

EXHIBIT B



## Kelly Strange Crawford

Partner

Direct: t: 973.451.8417 f: 973.451.8635 kcrawford@riker.com Reply to: Morristown

### Via Email

May 21, 2012

Adam M. Slater, Esq. Mazie, Slater, Katz & Freeman, LLC 103 Eisenhower Parkway Roseland, NJ 07068

Jeffrey Grand, Esq. Bernstein Liebhard LLP 10 East 40th Street New York, NY 10016 Jillian A. S. Roman, Esq. Cohen, Placitella & Roth, PC Two Commerce Square, Suite 2900 2001 Market Street Philadelphia, PA 19103

Bryan Aylstock, Esq. Aylstock, Witkin, Kreis & Overholtz, PLLC 17 East Main Street, Suite 200 Pensacola, FL 32502

Re: In Re Pelvic Mesh/Gynecare Litigation - CT 291

Counsel:

This letter will document the results (previously communicated to Cheryll Calderon) of the joint effort to confirm the final versions and approval dates of the patient brochures relating to the pelvic floor products to the best of our knowledge and ability to date. Though the documents are included in the productions to date, we reproduced them in Production 44, in color, with unique Bates numbers.

• Attachment I (ETH.MESH.03905968-ETH.MESH.03905975) = "Get the Facts, Be Informed" brochure copyrighted 2005 (woman with long brown hair, pearl earrings, white blouse on blue background cover), identified in Defendants' 2005 to 2009 copy review materials index as "GYNECARE PROLIFT\* Pelvic Floor Repair System Patient Brochure/Robin Osman," CR Item 1812, with an approval date of 11/9/2005. Last page of brochure states: "Ethicon, Inc. 2005 \*Trademark GPSO05". [Note that a version of this document was marked by Plaintiffs during depositions as Exhibit 428.]

Plaintiffs' Counsel May 21, 2012 Page 2

- Attachment 2 (ETH.MESH.03905976-ETH.MESH.03905991) = "Get the Facts, Be Informed" brochure copyrighted 2006 (woman with short blond hair and white sweater on blue and green cover), identified in Defendant's 2005 to 2009 copy review materials index as "GYNECARE PROLIFT\* Pelvic Floor Repair Systems Patient Brochure/Robin Osman," CR Item 2938, with an approval date of 11/15/2006. Last page of brochure states: "Ethicon, Inc. 2006 \*Trademark GPS005R".
- Attachment 3 (ETH.MESH.03905992-ETH.MESH.03906000) = "What's Happening Down There" brochure copyrighted 2007, identified in Defendants' 2005 to 2009 copy review materials index as "GYNECARE PROLAPSE\* Patient Brochure/Jackie Russo-Jankewicz," CR Item 3165 with an approval date of 2/7/2007. Last page of brochure states: "GPSO20".
- Attachment 4 (ETH.MESH.03906037-ETH.MESH.03906052) = "Stop Coping, Start Living" brochure copyrighted 2008 (two women, one with white sweater and one with beige jacket, on white background cover), identified in Defendants' 2005 to 2009 copy review materials index as "Pelvic Organ PROLAPSE Patient Brochure/Robin Osman," CR Item 2008-12-2, with an approval date of 10/22/2008. Last page of brochure states: "Ethicon, Inc. 2008 GPS005R1".
- Attachment 5 (ETH.MESH.03906001-ETH.MESH.03906020) = "Stop Coping, Start Living" brochure copyrighted 2009 (two women, pink blouse and blue blouse, on white background cover), identified in Defendants' 2009 to present GGM Blue index as "POP Patient Brochure/Kevin Frost," Task No. GPD-037-10-1/12, approval date 11/9/2009. Last page of brochure states: "Ethicon, Inc. 2009 GPD-037-10-1/12" and it includes Prosima.

Very truly yours,

Kelly S. Crawford/e Kelly S. Crawford

<sup>&</sup>lt;sup>1</sup> This same brochure was produced twice in color in Production 44. The second range was ETH.MESH.03906021-ETH.MESH.03906036.

### Pelvic Mesh Litigation In Use Copy Review Materials POP Patient Brochures

Year	SUBMISSION TITLE/SUBMITTER	CR Item #	Copy Approva	Production Start Bates	Production End Bates	Notes
2005	GYNECARE PROLIFT* Pelvic Floor Repair System Patient Brochure/Robin Osman	1812	11/9/2005	ETH.MESH.03905968	ETH.MESH.03905975	"Get the Facts, Be informed" brochure copyrighted 2005 with "Ethicon, Inc. 2005 *Trademark GPSO05" on last page
2006	GYNECARE PROLIFT* Pelvic Floor Repair Systems Patient Brochure/Robin Osman	2938	11/15/2006	ETH.MESH.03905976 and ETH.MESH.03906021	ETH MESH.03905991 and ETH.MESH.03906036	"Get the Facts, Be Informed" brochure copyrighted 2006 with "Ethicon, Inc. 2006 *Trademark GPS005R" on last page
2007	GYNECARE PROLAPSE* Patient Brochure/Jackie Russo-Jankewicz	3165	2/7/2007	ETH.MESH.03905992	ETH.MESH.03906000	"What's Happening Down There" brochure copyrighted 2007, with "GPSO20" on last page
2008	Pelvic Organ PROLAPSE Patient Brochure/Robin Osman	2008-1202	10/22/2008	ETH.MESH.03906037	ETH.MESH.03906052	"Stop Coping, Start Living" brochure copyrighted 2008 with "Ethicon, Inc. 2008 GPS005R1" marking on last page
2011	GPD-037-10_Patient Prolapse Brochure_CA.pdf/Kevin Frost	GPD_037-10- 1/12	11/9/2009	ETH.MESH.03906001	ETH.MESH.03906020	"Stop Coping, Start Living" brochure copyrighted 2011 with "Ethicon, Inc. 2009 GPD-037-10- 1/12" on last page and it includes Prosima

5/21/2012 Page 1